

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re of Application of: Eric J. BENJAMIN, Reinhardt B. BAUDY and Michael R. BRANDT  
Application No.: TBA Group Art No.:  
Filed: TBA Examiner:  
For: PHARMACEUTICAL COMPOSITIONS FOR INTRANASAL  
ADMINISTRATION OF [2-(8,9-DIOXO-2,6-DIAZABICYCLO[5.2.0]  
NON-1(7)-EN-2-YL)ALKYL] PHOSPHONIC ACID AND DERIVATIVES  
AND METHODS OF USE THEREOF  
Confirmation No.: TBA  
Customer Number: 25291

Mail Stop Patent Application  
Commissioner for Patents  
PO Box 1450  
Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT

This Information Disclosure Statement accompanies the new patent application submitted herewith of the following Inventors: Eric J. BENJAMIN, Reinhardt B. BAUDY, and Michael R. BRANDT;

For: **PHARMACEUTICAL COMPOSITIONS FOR INTRANASAL ADMINISTRATION OF [2-(8,9-DIOXO-2,6-DIAZABICYCLO[5.2.0]NON-1(7)-EN-2-YL)ALKYL] PHOSPHONIC ACID AND DERIVATIVES AND METHODS OF USE THEREOF.**

1. Preliminary Statements

In accordance with 37 CFR 1.97 and 1.98, Applicants submit herewith patents, publications, or other information of which they are aware, which they believe may be material to the examination of this application and in respect of which there may be a duty to disclose in accordance with 37 CFR 1.56. This Information Disclosure Statement is not to be construed as a representation that: (i) a search has been made; (ii) the information is material to the examination of this application; (iii) additional information material to the examination of this application does not exist; (iv) the information, protocols, results and the like reported by third parties are accurate or enabling; or (v) the information constitutes prior art to the subject invention.

2. ☐ Previously Cited Information

No copy of the patents, publications or other information cited on the attached form PTO-1449 is enclosed because it has been previously cited by or submitted to the Office in a prior application which is relied upon for an earlier filing date under 35 USC 120. Prior application is Application Number \_\_\_\_\_ filed on \_\_\_\_\_ of \_\_\_\_\_ for \_\_\_\_\_.

**CERTIFICATE OF MAILING 37 CFR §1.10**

I hereby certify that this paper and the documents referred to as enclosed therein are being deposited with the United States Postal Service on the date written below in an envelope as "Express Mail Post Office to Addressee" Mailing Label Number EU947816431US addressed to the Mail Stop Patent Application, Commissioner for Patents, PO Box 1450, Alexandria, VA 22313-1450.

April 7, 2004  
Date

Paula L. Dickey  
Paula L. Dickey

3. ☒ Newly Cited Information  
A legible copy of the patents, publications or other information cited on the attached form PTO-1449 is enclosed, except that if this patent application was filed or entered the national stage after June 30, 2003, no copy of a U.S. patent or U.S. patent application publication is enclosed.
4. ☐ Concise Explanation  
Documents cited above which are not in the English Language  
a. ☐ have been explained in the specification.  
b. ☐ have an abstract (or other concise explanation) in English enclosed or, if readily available, a translation into English of the document is enclosed.
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6. Customer Number 25291.

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Substitute for form 144B/PTO  INFORMATION DISCLOSURE STATEMENT BY APPLICANT  (use as many sheets as necessary)				<b>Complete if Known</b>	
				Application Number	To Be Assigned
				Filing Date	TBA
				First Named Inventor	Benjamin et al.
				Group Art Unit	
				Examiner Name	
Sheet	1	of	2	Attorney Docket Number	AM101252

U.S. PATENT DOCUMENTS						
Examiner Initials*	Cite No.	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number (If known)	Kind Code (If Known)			
	1.	5,168,103		Kinney et al.	12-01-1992	
	2.	5,990,307		Asselin et al.	11-23-1999	
	3.	6,011,168		Asselin et al.	01-04-2000	
	4.	5,240,946		Kinney et al.	08-31-1993	
	5.	5,624,898		William H. Frey, II	04-29-1997	
	6.	6,451,848	B1	Behl et al.	09-17-2002	
	7.	5,124,319		Baudy et al.	06-23-1992	
	8.	2003/0114444	A1	Brandt et al.	06-19-2003	

FOREIGN PATENT DOCUMENTS								
Examiner Initials*	Cite No.	Foreign Patent Document			Name of Patentee or Applicant of Cited document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T
		Office	Number	Kind Code (If Known)				
	9.	EP	0 496 561	A2	American Home Products Corp.	07-29-1992		<input type="checkbox"/>
	10.	WO	98/15542	A1	H. Lundbeck A/S	04-16-1998		
	11.	EP	0 994 107	A1	H. Lundbeck A/S	04-19-2000		
	12.	EP	0 778 023	A1	American Home Products Corp.	06-11-1997		
	13.	WO	99/06417	A1	American Home Products Corp.	02-11-1999		
	14.	WO	99/64041	A1	Advanced Medicine, Inc.	12-16-1999		
	15.	WO	03/065982	A2	Xenoport, Inc.	08-14-2003		
	16.	WO	03/031416	A2	Wyeth	04-17-2003		

OTHER PRIOR ART — NON PATENT LITERATURE DOCUMENTS				
Examiner Initials*	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.		T
	17.	KARLSTEN et al., Drug & Aging, 11(5), 398-412 (1997).		<input type="checkbox"/>
	18.	HAO et al., Pain, 66, 279-285 (1996).		
	19.	CHAPLAN et al., Pharmacology & Experimental Therapeutics, 280(2), 829-838 (1997).		
	20.	SUZUKI et al., Pain, 91, 101-109 (2001).		
	21.	BENNETT, Journal of Pain & Symptom Management, 19(1 Suppl.), S2-S6 (2000).		
	22.	SANG, Journal of Pain & Symptom Management, 19(1 Suppl.), S21-S25 (2000).		
	23.	PAL et al., Burns, 23(5), 404-412 (1997).		
	24.	ROGAWSKI et al., Trends in Pharmaceutical Sciences, 14, 325-331 (1993).		
	25.	NICHOLSON et al., Behavioural Pharmacology, 9, 231-243 (1998).		
	26.	MORI et al., Behavioural Brain Research, 119, 33-40 (2001).		
	27.	BARON et al., Psychopharmacology, 118, 42-51 (1995).		
	28.	FRANCE et al., Journal of Pharmacology & Experimental Therapeutics, 257(2), 727-734 (1991).		
	29.	FRANCE et al., European Journal of Pharmacology, 159, 133-139 (1989).		
	30.	OLNEY et al., Science, 254, 1515-1518 (1991).		
	31.	FIX et al., Experimental Neurology, 123, 204-215 (1998).		
	32.	BRADFORD et al., Stroke & Cerebral Circulation, Abstract (1998).		
	33.	MILLAN et al., Neuroscience Letters, 178, 139-143 (1994).		
	34.	KINNEY et al., J. Med. Chem., 41, 236-246 (1998).		
	35.	MCROBERTS et al., Gastroenterology, 120(7), 1737-1748 (2001).		
	36.	OLIVAR et al., Pain, 79, 67-73 (1999).		
	37.	RYGH et al., Pain, 93, 15-21 (2001).		
	38.	TANG et al., Nature, 401, 63-69 (1999).		
	39.	WEI et al., Nature, 4(2), 164-169 (2001).		

Examiner Signature		Date Considered	
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Substitute for form 144B/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (use as many sheets as necessary)				<b>Complete if Known</b>	
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	40.	CHAPLAN, S.R., Journal of Neuroscience Methods, 53, 55-63 (1994).			
	41.	BENNETT, Gary et al., Pain, 33, 87-107 (1988).			
	42.	HEWITT, David, The Clinical Journal of Pain, 16, S73-S79 (2000).			
	43.	WOOLF, et al., Pain, 44, 293-299 (1991).			
	44.	OLNEY, et al., Science, 244, 1360-1362 (1989).			
	45.	ABRAHAMS et al., Emerging Drugs, 5(4), 385-413 (2000).			
	46.	HERRLING, P.L., Academic Press, Chapter 1, 1-6 (1997).			
	47.	BAUDY et al., J. Med. Chem. 36, 331-342 (1993).			<input type="checkbox"/>
	48.	KRISTENSEN, et al., Database Biosis, Biosciences Information Service, Abstract XP002228851.			
	49.	BAUDY et al., J. Med. Chem. 44, 1516-1529 (2001).			
	50.	CHILDERS et al., Drugs of the Future, 27(7), 633-638 (2002).			
	51.	KRISTENSEN, et al., Pain, 51, 249-253 (1992).			
	52.	ABOU-GHARBIA, Abstract Paper, Am. Chem. Soc., 221 <sup>st</sup> MEDI 202 (2001).			
	53.	B.M. SWAHN et al., Bioorganic & Medicinal Chemistry Letters, 6(14), 1635-1640 (1996).			<input type="checkbox"/>
	54.	S.H. WILEN et al., Tetrahedron, 33, 2725-2736 (1977).			
	55.	C.R. BEHL et al., Advanced Drug Delivery Reviews, 29, 117-133 (1998).			
	56.	A. HUSSAIN, Advanced Drug Delivery Reviews, 29, 39-49 (1998).			
	57.	T. MOSCONI et al., Pain, 64, 37-57 (1996).			
	58.	M. BRANDT et al., The Journal of Pharmacology & Experimental Therapeutics, 296(3), 939-946 (2001).			
	59.	H. ZIA et al., Clinical Research & Regulatory Affairs, 10(2), 99-135 (1993).			
	60.	G.D. PARR, Pharmacy International, 4, 202-205 (1983).			
	61.	G.J. BENNETT et al., Pain, 33, 87-107 (1988).			
	62.	S.C. SUTTON et al., Pharmaceutical Research, 10(6), 924-926 (1993).			
	63.	S.R. CHAPLAN et al., Journal of Neuroscience Methods, 53, 55-63 (1994).			
	64.	F. MENNITI, et al., European Journal of Pharmacology, 331, 117-126 (1997).			
	65.	B. CHIZH et al., TRENDS in Pharmacological Sciences, 22(12), 636-642 (2001).			
	66.	S. BOYCE et al., Neuropharmacology, 38, 611-623 (1999).			
	67.	V. MUTEL et al., Journal of Neurochemistry, 70, 2147-2155 (1998).			

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